Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in June 2015.

Original Approvals

This section displays the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-417

Trade Name: CORAXIS™ Ingredients: Moxidectin

Sponsor: Bayer HealthCare LLC, Animal Health Division

Approval Date: June 6, 2015

Status: Rx
Route: Topical
Species: Dogs
Drug Form: Solution

Concentration: 2.5% moxidectin

Indications: For the prevention of heartworm disease caused by *Dirofilaria immitis*, and for

the treatment and control of *Ancylostoma caninum* (adults, immature adults, and fourth stage larvae), *Uncinaria stenocephala* (adults, immature adults, and

fourth stage larvae), Toxocara canis (adults and fourth stage larvae),

Toxascaris leonina (adults), and Trichuris vulpis (adults) in dogs and puppies

that are at least 7 weeks of age and that weigh at least 3 pounds.

Exclusivity: 3 years

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-262

Trade Name: Cerenia®

Ingredients: Maropitant citrate Sponsor: Zoetis Inc. Approval Date: June 17, 2015

This supplement provides for the extension of the number of days of consecutive use from "5 days" to "until resolution of acute vomiting" for the prevention of acute vomiting in dogs 7 months and older.

Sponsor Change

NADA Numbers: 038-200, 065-178, 065-496

Previous: Strategic Veterinary Pharmaceuticals, Inc.

New Sponsor: Phibro Animal Health Corp.

Drug Labeler Code: 066104

Withdrawal of Approval

NADA Number: 065-222

Sponsor: Hartz Mountain Products Corp.

Trade Name: Keet Life

Actions Taken by FDA Center for Veterinary Medicine The following corrections or additions to the list were completed in June 2015.

Ingredients: Chlortetracycline

This product is withdrawn because the product is no longer manufactured or marketed.